DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 18, 2015

SIEMENS HEALTHCARE DIAGNOSTICS
KATHLEEN DRAY-LYONS
REGULATORY AND CLINICAL AFFAIRS SPECIALIST
500 GBC DRIVE, P.O. BOX 6101
NEWARK, DE 19714

Re: K143720
Trade/Device Name: Dimension Vista MMB Assay, Dimension Vista 1500 System
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: JHY, JJE
Dated: July 31, 2015
Received: August 3, 2015

Dear Ms. Kathleen Dray-Lyons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143720

Device Name
• Dimension Vista® MMB (Mass creatine kinase MB isoenzyme) Assay
• Dimension Vista® 1500 System

Indications for Use *(Describe)*

Dimension Vista® MMB Assay:
The MMB method is an in vitro diagnostic test for the quantitative measurement of mass creatine kinase MB isoenzyme in human serum and plasma on the Dimension Vista® System for confirmation of acute myocardial infarction.

Dimension Vista® 1500 System:
The Siemens Healthcare Diagnostics Dimension Vista® 1500 System is an in vitro diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Dimension Vista® chemical and immunochemical applications use photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion-selective multisensor technology for clinical use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K143720

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer: Siemens Healthcare Diagnostics Inc.
500 GBC Drive
Newark, DE 19714

Contact Information: Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Email: kathleen.a.dray-lyons@siemens.com

Date of Preparation: September 15, 2015

2. Device Names:

- Dimension Vista® MMB (Mass creatine kinase MB isoenzyme)
- Dimension Vista® 1500 System

Classifications:

- 21 CFR §862.1215; Creatine phosphokinase/creatine kinase or isoenzymes test system, Class II
- 21 CFR §862.2160; Analyzer, chemistry (photometric, discrete), For Clinical Use, Class I

Product Codes:

- JHY
- JJE

Panels:

- Chemistry

3. Identification of the Predicate Devices:

Dimension Vista® MMB (Mass creatine kinase MB isoenzyme) - K970343
Dimension Vista® 1500 Integrated System - K051087

4. Device Description:

Dimension Vista® MMB Assay:

The MMB method is a homogeneous sandwich chemiluminescent immunoassay based on LOCI® technology. LOCI® reagents include two synthetic bead reagents and a biotinylated antimass creatine kinase MB isoenzyme monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and contains photosensitive dye. The second bead reagent (Chemibeads) is coated with a second anti-mass creatine kinase MB isoenzyme monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a beadmass creatine kinase MB isoenzyme-biotinylated antibody sandwich. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex by light at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the mass creatine kinase MB isoenzyme concentration in the sample.

The Dimension Vista® 1500 System:

The Dimension Vista® 1500 System is a floor model, fully automated, microprocessor-controlled, integrated instrument system that uses prepackaged Flex reagent test cartridges to measure a variety of analytes in human body fluids. The system is a multi-functional analytical tool that processes chemical and immunochemical methodologies, utilizing photometric, turbidimetric, chemiluminescence, nephelometric, and integrated ion selective multisensor detection technologies for clinical use. The Dimension Vista® 1500 System can analyze up to 1500 tests/hour (typical, depending on the method mix) using a variety of analytical detection capabilities. Dimension Vista® 1500 System detection technologies are: Photometric, Turbidimetric, Chemiluminescent, Nephelometric, Multisensor, ion selective technology

5. Device Intended Use:

Dimension Vista® MMB Assay:

The MMB method is an *in vitro* diagnostic test for the quantitative measurement of mass creatine kinase MB isoenzyme (EC 2.7.3.2) in human serum and plasma on the Dimension Vista® System for confirmation of acute myocardial infarction.

Dimension Vista® 1500 System:

The Siemens Healthcare Diagnostics Dimension Vista® 1500 System is an *in vitro* diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Dimension Vista® 1500 System chemical and immunochemical applications use photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion-selective multisensor technology for clinical use.

6. Medical device to which equivalence is claimed:

The modified Dimension Vista® MMB test system for use on the Dimension Vista® 1500 System with the new photomultiplier tube (PMT) is substantially equivalent to the currently marketed Dimension Vista® MMB assay (K970343) on the Dimension Vista® 1500 Integrated System (K051087).

A comparison of the similarities and differences between the devices is provided in the following tables:

Dimension Vista® MMB Assay
Similarities and Differences

Feature	Predicate Dimension Vista® MMB Flex® reagent cartridge	Proposed Dimension Vista® MMB Flex® reagent cartridge
Intended Use	**Dimension Vista® MMB Assay:** The MMB method is an *in vitro* diagnostic test for the quantitative measurement of mass creatine kinase MB isoenzyme (EC 2.7.3.2) in human serum and plasma on the Dimension Vista® System for confirmation of acute myocardial infarction.	Same
Assay Range	0.5–300 ng/mL	1.0 – 300 ng/mL
Sample Type	Human serum and plasma	Same
Technology	LOCI® technology	Same
Sample size	5 µL	Same
Reagents and antibody	Biotinylated monoclonal antibody, mass creatine kinase MB isoenzyme Chemibeads, Streptavidin Sensibeads, assay buffer	Same

Similarities between the predicate Dimension Vista® 1500 System and the Modified Dimension Vista® 1500 Integrated System with new PMT:

Feature	Predicate Dimension Vista® 1500 Integrated System (Current)	Propose Device Dimension Vista® 1500 System (Modified with new PMT)
Intended Use	**Dimension Vista® 1500 Integrated System** The Siemens Healthcare Diagnostics Dimension Vista® Integrated System is an *in vitro* diagnostic device intended to duplicate manual analytical procedures such as pipetting, mixing, heating, and measuring spectral intensities to determine a variety of analytes in human body fluids. Dimension Vista® chemical and immunochemical applications use photometric, turbidimetric, chemiluminescence, nephelometric and integrated ion-selective multisensor technology for clinical use.	Same
System Control	Fully automated and controlled by microprocessors	Same
User Interface	Contains graphical user interface screens	Same
Detection Technologies	Contains a photometer and a multisensor electrode for performing photometric tests, and electrolyte tests. It also has a LOCI® module for immunoassay tests.	Same
Reagents	Uses pre-packaged Flex® reagent cartridges. Reagents are hydrated and stored on-board the instrument	Same
Temperature	Reagents are stored at 2 - 8ºC. Reactions are controlled at 37ºC.	Same
Operating System	Windows Operating System	Same
Photomultiplier tube used to count the signal in the chemiluminescent methods	❖ Contains a faceplate ❖ Contains a photocathode ❖ Contains an anode at end	Same

Differences between the predicate Dimension Vista® 1500 System and the Modified Dimension Vista® 1500 Integrated System with new PMT:

Feature	Predicate Dimension Vista® 1500 Integrated System (Current)	Propose Device Dimension Vista® 1500 (Modified with new PMT)
Photomultiplier tube used to count the signal in the chemiluminescent methods	Vendor: Excelitas Multiplier channel: Enhanced Glass Single Surface Tube	Vendor: Hamamatsu Multiplier channel: multiple dynodes
Component Area Network (CAN Board)	Included in current Dimension Vista® 1500 Integrated System	Updated to also be compatible with new PMT

7. Performance Characteristics

Method Comparison:

A split sample method comparison between the Dimension Vista® MMB assay (K970343) on the modified Dimension Vista® 1500 System with the new PMT and the predicate Dimension Vista® 1500 Integrated System (K051087), was performed with 111 native de-identified human serum and plasma samples across the assay range (1.0 to 300 ng/mL). Analysis of the results yielded the following:

Method	Predicate Sample Range (ng/mL)	Slope (95% CI)	Intercept ng/dL (95% CI)	Correlation Coefficient (std linear regression)	n
MMB (Passing Bablok)	1.0 – 274.0	0.99 (0.98 – 0.99)	-0.16 (-0.20 – -0.10)	Not applicable	111
MMB (linear regression)	1.0 – 274.0	0.97	0.64	0.999	111

Precision:

Reproducibility testing was conducted in accordance with the CLSI/NCCLS Approved Guideline for User Evaluation of Precision Performance of Clinical Chemistry Devices EP5-A2. For each test level, a single test from two independent cups was analyzed twice per day for 20 days. The repeatability and within-lab standard deviations were calculated by the analysis of variance method.

Typical precision observed on the modified Dimension Vista® 1500 System is summarized below:

Modified Dimension Vista® 1500 System (new PMT)

Material	Mean ng/mL	Repeatability		Within-Lab Precision	
		SD	%CV	SD	%CV
Thermo CardioImmune XL Liquid Assayed Cardiac Marker Control					
QC1	8.66	0.15	1.72	0.22	2.59
QC2	24.13	0.36	1.50	0.56	2.30
QC3	70.73	0.91	1.28	1.27	1.80
Plasma Pool 1	3.26	0.15	4.71	0.19	5.99
Plasma Pool 2	6.15	0.15	2.45	0.21	3.40

Linearity

Linearity across the assay range (1.0 to 300 ng/mL) was confirmed according to CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement, by testing a sample with a high concentration of MMB. This sample was serially diluted with a low concentration sample producing ten test samples ranging from 0 to 313.5 ng/mL. Each dilution was assayed in replicates of five. Data were analyzed using linear regression analysis [x-axis: theoretical concentration versus y-axis: measured concentration]. 2^{nd} - and 3^{rd} -order polynomial regressions of the mean observed analyte values vs. expected concentrations were generated. A summary of the linearity data is presented below.

Range of Samples	Slope	Intercept	Correlation Coefficient.	N
0 – 313.5 ng/mL	1.004	0.170	0.999	10

LoB, LoD and LoQ

The Limit of Blank (LoB) was calculated to be 0.4 ng/mL [0.4 µg/L]. LoD is the lowest concentration of analyte that can be detected reliably, while LoB is the highest concentration that is likely to be observed for a blank sample.
The Limit of Detection (LoD) was determined to be 0.8 ng/mL [0.8 µg/L]. The proportions of false positives (α) was less than 5% and false negatives (β) less than 5%, based on 260 determinations, with 60 blank replicates and 200 low level replicates.

The limit of quantitation (LoQ) corresponds to a within-laboratory imprecision coefficient of variation (CV) of ≤ 20% at a mass creatine kinase MB isoenzyme concentration ≤ 1.0 ng/mL [1.0 µg/L]. Refer to Attachment 1 and 2 for a copy of the LOB, LOD and LOQ protocol and line data respectively.

Specificity

Specificity studies were not performed, because specificity is antibody dependent and there were no changes to the MMB assay antibody or concentration of the antibody conjugates. In addition, the Dimension Vista® 1500 System new photomultiplier tube, which is used to count the signal, would not impact assay specificity. Refer to the original 510(k) clearance, k970343 for the specificity data.

8. Conclusion:

The proposed modified Dimension Vista® MMB test system for use on the Dimension Vista® 1500 System is substantially equivalent to the current legally marketed device based on intended use, principle and the performance characteristics above.